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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,661	KOCSIS ET AL.	
	Examiner	Art Unit	
	JENNIFER MYONG M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *5, 7, 8, 12, 13, 15, 17, 21 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,9-11,14,16,18-20 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group VI, claims directed to a pharmaceutical **composition** which comprises a sodium channel blocker in combination with a selective serotonin uptake inhibitor **and** the **use** of the composition for the treatment of **chronic pain**, with l**amotrigine** as a species of sodium channel blocker and **sertraline** as a species of a selective serotonin uptake inhibitor is acknowledged. The traversal is on the ground(s) that the single general inventive concept that ties all of the claims together is the co-administration of sodium channel blockers and selective serotonin uptake inhibitors, not the various conditions being treated.

This is not found persuasive because the each of the compounds to be utilized lack the same or corresponding special technical features because they lack common chemical structural moiety having different chemical/physical properties. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility. Further, the medical disorders to be treated therein lack same special technical features because they have different known etiologies. Therefore, the restriction under 35 U.S.C. 121 and 372 made in the previous Office Action is deemed proper and made final.

Accordingly, claims 1-4, 6, 9-11, 14, 16, 18-20 and 22 being examined to the extent of Applicants' elected species and claims 5, 7, 8, 12, 13, 15, 17, 21 and 23 are withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 and 14 provide for the use of a sodium channel blocker and a selective serotonin uptake inhibitor for the treatment of chronic pain, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-11 and 14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.

1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

To accelerate the prosecution of the instant Application, the "use" claims have been examined as "method of use" claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 9-11, 14, 16, 18-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzgerald et al. (1998) in view of Waldman et al. (1998) and further in view of Carson et al. (U.S.Patent No. 6,191,142 B1).

Fitzgerald et al. teach that lamotrigine is a novel anticonvulsant but effective in the management of chronic pain refractory to more conventional treatment. Fitzgerald et al. teach that the current indication of lamotrigine includes the treatment of neuropathic pain. (title, see under Lamotrigine). Fitzgerald et al. teach that the Lamotrigine is well absorbed after oral use with bioavailability approaching 80%. Fitzgerald et al. teach that the dosage of lamotrigine for the treatment of chronic pain at 25mg per day and increase by 25mg weekly until a dosage of 200mg per day is reached. (under Lamotrigine, pharmacokinetics and dose guidelines).

Fitzgerald et al. lack sertraline.

Waldman et al. teach that both lamotrigine and sertraline is useful for the treatment of neuropathic pain.(page 59, table 2, under antidepressants, under anticonvulsants).

Carson et al. report that neuropathic pain is defined as **pain** caused by aberrant somatosensory processing in the peripheral or central nervous system that is **chronic** or debilitating. (column 1, lines 21-30).

To employ combinations of lamotrigine and sertraline to treat chronic pain condition such as neuropathic pain would have been obvious because all the components are well known individually for treating chronic pain conditions such as neuropathic pain. It would be expected that the combination of components would treat chronic pain conditions such as neuropathic pain as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)).

One of ordinary skill in the art would have combined the analgesic agents by known methods and that in combination, each element merely would have performed the same analgesic activity as it did separately. The convenience of putting the compounds having the same analgesic activity of lamotrigine and sertraline together in one dosage form, though perhaps a matter of great convenience does not produce a "new" or "different" function and to those skilled in the art, the use of the old elements in combination would have been obvious. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is

(571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Examiner, Art Unit 1617

Jmk
July 31, 2009